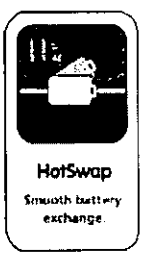
HAMILTON MEDICAL

APR - 3 2012

HAMILTON·T1

SPECIAL 510(k) SUMMARY K 120670



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CONTACT PERSON:	Ralph Aguila Regulatory Affairs / Quality Engineer Phone: +49 171 401 7192 Fax: +41 81 660 60 20 e-mail: raguila@hamilton-medical.ch
ESTABLISHMENT REGISTRATION NUMBER:	3001421318
PREPARATION DATE:	2012-02-23
TRADE NAME:	HAMILTON-T1
COMMON NAME:	Continuous Ventilator
CLASSIFICATION NAME:	CLASS II Ventilator, Continuous
REGULATION NUMBER:	21 CFR 868.5895
PRODUCT CODE:	CBK
PREDICATE DEVICE:	HAMILTON-TC1 510(k) Number: **K112006**

DEVICE DESCRIPTION

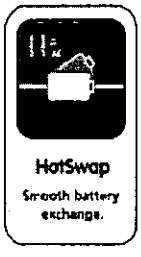
The HAMILTON-T1 is designed for adults and pediatrics requiring invasive or noninvasive ventilation support. Due to its compact design, a fully-loaded weight of only 6.5 kg (14.3 lbs), a twin hot-swappable battery supply, and a built-in turbine; the HAMILTON-T1 can accompany a ventilated patient everywhere within the hospital or outside the hospital when transport is needed. The HAMILTON-T1 can run using AC or DC power. It does not need compressed air or O_2 to drive the pneumatics, which reduces the weight load in the aircraft needed to operate the ventilator.

Since the HAMILTON-T1 has been tested and evaluated for flight and high-altitude environments, it can be also used during patient transfer by emergency rescue vehicles, fixed-wing aircraft, or helicopter. This makes the HAMILTON-T1 especially relevant for Aeromedical Evacuations and Medevac operations.

The HAMILTON-T1 ventilator uses the same graphical user interface (GUI) used by the HAMILTON-C2 and HAMILTON-G5, featuring a touchscreen "Ventilation Cockpit"; this provides the exact information that the user needs and helps focus on what is important. In addition, the HAMILTON-T1 includes the ASV ventilation-mode which automatically applies lung-protective strategies, reduces the risk of operator error, and promotes early weaning.

The HAMILTON-T1's microprocessor system controls gas delivery and monitors the patient. The gas delivery and monitoring functions are cross-checked by an alarm controller. This cross-checking helps prevent simultaneous failure of these two main functions and minimizes the possible hazards of software failure.

The HAMILTON-T1 is intended as a transport ventilator, based on the existing HAMILTON-C2, with minor adaptations to make the HAMILTON-T1 capable of being used in high-altitude flight environments. The HAMILTON-T1's changes include the following:



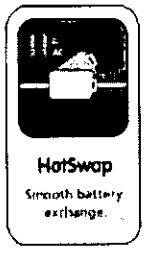
1. The HAMILTON-T1 software is identical to the HAMILTON-C2's software, except that some of the options are not available with the HAMILTON-T1, (e.g. Neonatal Ventilation & nCPAP-PS). Other features like Trends & Loops, NIV, NIV-ST, APRV, and DuoPAP are standard with the C2, but are only optional with the HAMILTON-T1.
2. The HAMILTON-T1 has increased immunity from EMI, including >30 V/m. It also has extra safety features for the EMD, ESD, and RFI environments found on aircraft.
3. The unit is contained within an impact resistant case which protects the controls from damage and inadvertent manipulation. The enclosure for the HAMILTON-T1 has been ruggedized to withstand shock, vibrations, water ingress, and drops from >1 meter heights.
4. The HAMILTON-T1 was tested for use in fixed and rotary-wing aircraft.. Because mechanical ventilation can be challenging during air-medical transport, particularly due to the impact of changing barometric pressure with different altitude levels, the HAMILTON-T1 automatically compensates for altitude changes. Adjusting provided- and measured-patient volumes accordingly, thereby eliminating the need for manual calculation and reducing the risk of error.
5. The HAMILTON-T1 has a "lock-button" which prevents an inadvertent change of settings. If screen lock is active, the following items are inactive: Touchscreen, Power/Standby switch, Print-screen key, Press-and-turn knob. Active are Alarm Silence, Manual Breath, O_2 enrichment, Nebulizer. To switch off power, the user must press the On/Off button for > 3 s.

INTENDED USE

The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics.

Intended areas of use:

- In the intensive care ward or in the recovery room.
- For emergency medical care or primary care.
- During transport within and outside the hospital.
- During transfer by rescue vehicles, jet or helicopter.



The HAMILTON-T1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

FAA REGULATIONS

In accordance with the US Department of Transportation (DOT) and the Federal Aviation Administration (FAA), along with their rules on the "Use of Respiratory Assistive Devices on Aircraft", the HAMILTON-T1 meets the applicable safety requirements for Medical Portable Electronic Devices (M-PED) by not exceeding the maximum level of radiated radio frequency interference as described in the RTCA/DO 160F, Section 21, Category M.

DISCUSSION ON THE NON-CLINICAL TESTS

The non-clinical test results show that the HAMILTON-T1 is safe and effective for its intended use. The ventilator was further subjected to waveform performance testing as described in the standard ASTM F1100-90. The results of the software verification and validation testing demonstrate that all specified requirements have been implemented correctly and completely.

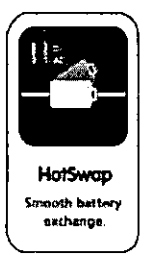
Below is a list of standards and guidance documents recognized by FDA to establish the basis of safety and effectiveness for the HAMILTON-T1:

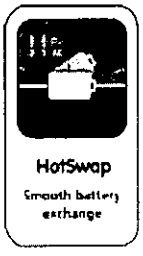
	Draft Reviewer Guidance for Ventilators.1995.
IEC 60601-1	General Requirements for Safety.
IEC 60601-1-2	Electromagnetic Compatibility.
IEC 60601-1-4	Programmable electrical medical systems.
IEC 60601-1-8	Alarm Systems
IEC 60601-2-12	Critical Care Ventilators.
IEC 62304	Software life-cycle processes.
IEC 62366	Application of usability engineering to medical devices.
ISO 5356-1	Conical connectors: Part 1: Cones and sockets.
AAMI/ANSI HE75	Human factors engineering. Design of medical devices.
EN ISO 14971	Application of risk management to medical devices.

Other internationally recognized standards which the HAMILTON-T1 meets or exceeds:

RTCA/DO-160F: 2007	Environmental Conditions and Test Procedures for Airborne Equipment. Equivalent to EUROCAE/ED-14F.
Section 7	Operational Shocks and Crash Safety
Section 8	Vibration
Section 16.6	Normal surge voltage (DC). Abnormal operating conditions (DC). Low voltage conditions (DC). Abnormal surge voltage (DC).
Section 17	Voltage spikes, 28 VDC
Section 18.3.1	DC input power leads
Section 19.3.1	Magnetic field induced into equipment by the aircraft 400 Hz power systems in vicinity of the device
Section 20	Radio Frequency Susceptibility (Radiated and Conducted)
Section 21	Maximum level of conducted RF interface - Power line. Maximum level of radiated RF interface. Category M.
Section 25	Electrostatic Discharge & Radiated Electromagnetic Field

EN ISO 13485	Medical devices -- Quality management systems.
EN ISO 9001	Quality management systems.
EN ISO 5359	Low-pressure hose assemblies for use with medical gases.
EN 794-1	Particular requirements for critical care ventilators.
EN 794-3	Particular requirements for emergency and transport ventilators. Equal to EN 60068-2-6; -29; -64.
EN 1789	Medical vehicles and their equipment - Road ambulances.
EN 13718-1	Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances
IEC 62133	Battery Safety. Non-Spillable.
ASTM F1100-90	Standard Specification for Ventilators Intended for Use in Critical Care (for waveform standard analysis)
MIL-STD-461E	RS101, CS114 (curve #3), and RE101 (Army 7-cm limit).





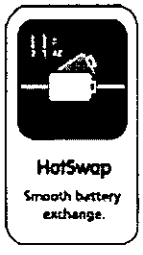
	Hamilton Medical HAMILTON-T1	Dräger Oxylog 3000+	CareFusion EnVe
Biphasic breathing	Yes	No	Yes
Advanced biphasic ventilation modes DuoPAP / APRV	Yes	No	No
Closed-Loop Ventilation with ASV	Yes	No	No
Smart Apnea Backup	Yes	No	No
Breathing circuit compensation	Yes	No	No
Nebulizer	Yes	No	Yes
Expiratory Trigger Sensitivity	Yes	No	Yes
CO_2 measurement (sidestream and mainstream)	Yes	No	No
Volumetric capnography	Yes	No	No
Dynamic Lung	Yes	No	No
VentStatus Window	Yes	No	No
Interface to monitoring system or PDMS	Yes	No	Yes
FiO_2 Range	21% - 100%	40% - 100%	21% - 100%
Tidal Volume	20 - 2,000 mL	50 – 2,000 mL	50 – 2,000 mL
Peak Flow	210 L/min	100 L/min	180 L/min

Comparison table between two transport ventilators and the proposed device: the HAMILTON-T1, Dräger 3000+, and CareFusion EnVe.

The intended use statement for the HAMILTON-T1 ventilator is equivalent to the predicate device. The technological characteristics (i.e., design, material, energy source) and performance specifications of the HAMILTON-T1 ventilator are equivalent to those of the predicate device. One of the tests used to evaluate the HAMILTON-T1 in a high-altitude, low-pressure environment, was to place the HAMILTON-T1 inside an altitude chamber to test the effects on the sensors and the ventilator measurements & readings.

The intended use of the HAMILTON-T1 is covered by the referenced predicate device. The technical characteristics of the HAMILTON-T1 do not raise any new questions regarding the safety or effectiveness of ventilators. The HAMILTON-T1's software has gone through verification/validation tests. A complete revision level history, hazard analysis, and a traceability analysis linking requirements to validation were done. The conclusions drawn from the non-clinical tests demonstrate that the HAMILTON-T1 is as safe, as effective, and performs as well as the legally marketed device. The HAMILTON-T1 is, therefore, considered to be substantially equivalent to the currently marketed predicate device which has been previously cleared by FDA.

The only reason for this Special 510(k) submission is due to a name change from the HAMILTON-TC1 (K112006) to the HAMILTON-T1 (proposed device).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Mr. Ralph Aguila
Regulatory Affairs / Quality Engineer
HAMILTON MEDICAL AG
Via Crusch 8
Bonaduz, 7402
SWITZWERLAND

APR - 3 2012

Re: K120670
Trade/Device Name: HAMILTON-T1
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: February 28, 2012
Received: March 5, 2012

Dear Mr. Aguila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K 120670

Device Name: HAMILTON-T1

Indication for Use: The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics.

Intended areas of use:

- In the intensive care ward or in the recovery room.
- For emergency medical care or primary care.
- During transport within and outside the hospital.
- During transfer by rescue vehicles, jet or helicopter.

The HAMILTON-T1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120670